

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

BIOSIGNIA, INC, )  
                        )  
                        )  
Plaintiff,         )  
                        )  
                        )  
v.                     ) 1:12CV1129  
                        )  
                        )  
LIFE LINE SCREENING OF )  
AMERICA, LTD; and HEALTH )  
IMPROVEMENT SOLUTIONS, INC., )  
                        )  
                        )  
Defendants.         )

**MEMORANDUM OPINION AND RECOMMENDATION  
OF UNITED STATES MAGISTRATE JUDGE**

This matter is before the court for a recommended ruling on the motion of Plaintiff BioSignia, Inc. (“BioSignia”) for a Preliminary Injunction as to Defendant Life Line Screening of America, Ltd. (“Life Line”) pending trial (Docket Entry 33).<sup>1</sup> Defendant Life Line opposes the motion. Plaintiff filed two affidavits of John Williams (Docket Entries 34, 37) in support of its motion and a response affidavit of Mark Ruby (Docket Entry 44). Additionally, Defendant Life Line Screening of America, Ltd (“Life Line”) filed declarations of Marianne O’Connell and Sara Zywicki (Docket Entries 42, 43) in support of its opposition to BioSignia’s motion. The court held a hearing on July 17, 2013, at which all parties appeared through counsel and presented oral argument.<sup>2</sup> For reasons set forth

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<sup>1</sup> Pursuant to 28 U.S.C. § 636(b)(1), United States Magistrate Judges may not dispose of motions for injunctive relief but may enter recommendations as to such motions.

<sup>2</sup> Counsel for Defendant Health Improvement Solutions (“HIS”) was present at the hearing. However, the motion for injunctive relief does not pertain to HIS. In this recommendation, therefore, any reference to Defendant refers to Life Line unless otherwise noted.

below, the Court determines that Plaintiff's motion for a preliminary injunction should be denied.

## II. BACKGROUND

Plaintiff began this action with the filing of its complaint on October 22, 2012. (Docket Entry 1.) In the complaint, Plaintiff asserts three claims: (1) breach of contract, (2) breach of duty of good faith, and (3) unfair and deceptive trade practices. Essentially, Plaintiff alleges that Life Line and HIS “illegally reverse-engineered BioSignia’s health risk assessment product, Know Your Number, in creating Life Line’s 6 For Life health risk assessment product.” (Pl.’s Mem. Supp. Mot. for Prelim. Inj. at 2, Docket Entry 35.)

According to the allegations in the complaint, BioSignia is a leader in the development and creation of advanced risk assessment solutions. (Compl. ¶ 9.) BioSignia developed the “first multiple disease health risk assessment (“HRA”) product and service.” (*Id.* ¶ 12.) Life Line is the nation’s leading provider of community-based preventive health screening services. (*See* First Declaration of Sara Zywicki ¶ 6, Docket Entry 43.) In order to offer more comprehensive services, Life Line decided to do business with BioSignia and utilize its health risk assessment product, Know Your Number (“KYN”), in Life Line’s health screenings. (Zywicki Decl. ¶ 18.) The parties entered into an initial Mutual Non-Disclosure Agreement (“NDA”) in June 2008. (Compl. ¶ 32.) In November 2009, the parties entered into a new Mutual Confidential and Non-Disclosure Agreement (“Agreement”). (Compl. ¶ 56.)

When Life Line customers purchased the KYN assessment tool at a health screening, Life Line forwarded the relevant data and readings to BioSignia. Biosignia then

processed the data through its proprietary mathematical formula, or algorithm, and returned output reports to Life Line to be passed on to the participant. (Zywicki Decl. ¶¶ 26-28.) Life Line was never in possession of the KYN algorithm. (*Id.* at ¶ 23.)

The parties entered into a licensing agreement and a confidentiality non-disclosure agreement in 2009 (“Life Line Agreement”) pursuant to which Life Line was prohibited from reverse-engineering BioSignia’s intellectual property. (Compl. ¶ 61.) Under this agreement, any products created by Life Line which were derivative of BioSignia intellectual property would become the property of BioSignia. (*Id.* ¶ 64.)

Due to various business reasons, Life Line decided to part ways with BioSignia and develop its own HRA program. (Zywicki Decl. ¶ 34; First Decl. of Marianne O’Connell ¶¶ 14-15, Docket Entry 42.) Ultimately, Life Line hired HIS to develop an HRA specifically for Life Line. (Zywicki Decl. ¶ 36; O’Connell Decl. ¶ 16.) The HRA developed by HIS and used by Life Line is called “6 For Life.” Life Line began using this product in 2011. (Zywicki Decl. ¶ 37; O’Connell Decl. ¶ 16.)

BioSignia alleges that Life Line’s development of 6 For Life breached the Life Line Agreement because the product was a reverse-engineered copy of KYN. (Compl. ¶ 164, Docket Entry 1.) Further, BioSignia alleges that because 6 For Life is a derivative product of KYN, under the Agreement BioSignia is entitled to ownership of 6 For Life. (*Id.* ¶ 165.) Additionally, BioSignia alleges that Life Line’s conduct in obtaining BioSignia’s trade secrets and intellectual property under false pretenses so as to reverse engineer a competitive product amounted to unfair and deceptive trade practices in violation of the North Carolina

Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1(a). (Compl. ¶¶ 88, 185-189.)

In its motion for a preliminary injunction, BioSignia asserts that Life Line has continued to refer to KYN in its marketing materials and on its website. According to BioSignia, <sup>6</sup> For Life is simply a knock-off of KYN and that as a result of Life Line's conduct, BioSignia's revenue from KYN has significantly diminished. BioSignia contends that Life Line's continued use of BioSignia's intellectual property has caused and will "continue to cause irreparable harm to BioSignia by causing confusion in the marketplace; permanently depriving BioSignia of customers; depriving BioSignia and its product of goodwill; and depriving BioSignia of its competitive advantage . . ." (Mot. for Prelim. Inj. ¶ 10, Docket Entry 33.)

## II. DISCUSSION

### A. Standard of Review

A party seeking a preliminary injunction must establish all four of the following elements: (1) he is likely to succeed on the merits; (2) he is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in his favor; and (4) an injunction is in the public interest. *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008); *Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 575 F.3d 342, 346-47 (4th Cir. 2009), overruling *Blackwelder Furniture Co. of Statesville v. Seelig Mfg. Co.*, 550 F.2d 189 (4th Cir. 1977).<sup>3</sup> A party must make a clear showing that he is likely to succeed on the merits of his

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<sup>3</sup> The original decision in *Real Truth* was vacated by the Supreme Court for further consideration in light of *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310 (2010). However, the Fourth Circuit reissued its opinion on Parts I and II of its earlier opinion in the case, 575 F.3d at 345-47, stating the

claim. *Winter*, 555 U.S. at 20; *Real Truth*, 575 F.3d at 345-46. Similarly, he must make a clear showing that he is likely to be irreparably harmed absent injunctive relief. *Winter*, 555 U.S. at 20-22; *Real Truth*, 575 F.3d at 347. Only then does the court consider whether the balance of equities tips in the favor of the party seeking the injunction. See *Real Truth*, 575 F.3d at 346-47. Finally, the court must pay particular regard to the impact of the extraordinary relief of an injunction upon the public interest. *Real Truth*, 575 F.3d at 347 (quoting *Winter*, 555 U.S. at 23-24).<sup>4</sup>

## B. Analysis

Here, BioSignia has not made a clear showing that there is a likelihood that it will succeed on the merits. Plaintiff's reliance on three sources of proof is simply not enough to show that BioSignia will succeed. First, Plaintiff relies on the allegations in the complaint to show to show that Life Line breached the Agreement between the parties:

BioSignia's Verified Complaint specifically states that Life Line breached the Life Line Agreement by misconduct including, but not limited to: (1) sharing BioSignia's information during the development of the knockoff product, while working closely with Defendant, including how KYN worked, technical specifications, trigger values for outputs, how the algorithm could be modified, background information and information regarding how KYN handles specific difficult patient inputs; (2) using confidential information

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facts and articulating the standard for issuance of a preliminary injunction, before remanding it to the district court for consideration in light of *Citizens United*. See *The Real Truth About Obama, Inc. v. Fed. Election Comm'n*, 607 F.3d 355 (4th Cir. 2010).

<sup>4</sup> Both parties misstate the proper standard for the awarding of a preliminary injunction, citing pre-*Winter* caselaw. Previously, the Fourth Circuit relied on a sliding scale approach under *Blackwelder* which allowed a plaintiff to obtain an injunction with a strong showing of a probability of success on the merits even if he demonstrated only a possibility of irreparable harm. In the wake of the Supreme Court decision in *Winter*, however, the *Blackwelder* balancing approach is no longer the appropriate standard in the Fourth Circuit. *Real Truth*, 575 F.3d at 347. While the Fourth Circuit has not expressly required that a movant prove success on the merits is "more likely than not" in order to meet the standard, it is clear that the requirement is "far stricter than the *Blackwelder* requirement that the plaintiff demonstrate only a grave or serious question for litigation." *Real Truth*, 575 F.3d at 345-46.

obtained from BioSignia for a purpose not permitted by the Life Line Agreement – under the Life Line Agreement, all information disclosed pursuant to the Life Line Agreement was considered “confidential”; (3) reverse engineering KYN to produce a competitive product; (4) conflating BioSignia’s products and materials with its own, creating a substantial likelihood of confusion between the products; and (5) creating an output that is substantially similar to BioSignia’s, which would convince a reasonable person that both sets of reports, along with their associated results, were generated from the same HRA program.

(Pl.’s Mem. at 14-15, citing Compl. ¶ 164; ¶¶ 77-128.)

Plaintiff cannot show the likelihood of success on the merits simply by relying on allegations in the complaint. Moreover, although Plaintiff is asserting a breach of contract claim, the contracts themselves are not in the record. *See Allstate Ins. Co. v. Warns*, Civil No. CCB-11-1846, 2012 WL 681792 at \*14 (D. Md. Feb. 29, 2012) (““The sufficiency of factual evidence may be a factor in determining likelihood of success on the merits”), citing *Marshall Durbin Farms, Inc. v. Nat'l Farmers Org., Inc.*, 446 F.2d 353, 357 (5th Cir. 1971) ([D]istrict courts have shown appropriate reluctance to issue [preliminary injunctions] where the moving party substantiates his side of a factual dispute on information and belief.”) and *Advocacy Org. for Patients & Providers v. Mercy Health Servs.*, 987 F. Supp. 967, 974 n. 13 (E.D. Mich. 1997) (finding plaintiffs were not likely to succeed on the merits because, in part, plaintiffs’ pleadings were an amalgamation of ‘information, knowledge and belief’”).

Plaintiff’s reliance on the affidavits of John Williams is similarly unavailing. These affidavits contain unsupported conclusions and offer no direct proof that Life Line created a derivative product in violation of the agreements between the parties. In fact, Mr. Williams’ affidavits primarily deal with stray references to KYN on Life Line’s website and other social media which have since been removed.

Finally, Plaintiff relies on the affidavit of Joseph Leutzinger, submitted by HIS in support of its motion to dismiss on jurisdictional grounds. (Aff. of Joseph A. Leutzinger, Ph.D, Docket Entry 17.) The court has reviewed Dr. Leutzinger's affidavit, which is filed under seal. The affidavit simply does not support the inferences and conclusions advanced by Plaintiff in its brief in support of the motion for preliminary injunction. For instance, Plaintiff cites Dr. Leutzinger's statement that “[i]n 2011 HIS delivered its final work product to Life Line for use by Life Line in developing Life Line's HRA.” (*Id.* ¶ 20.) This statement simply does not support BioSignia's assertion that “it has become clear that Life Line collaborated with the other defendants to reverse-engineer and develop a knockoff that competes with BioSignia's Know Your Number product.” (Pl.'s Mem. at 15, Docket Entry 35.) Life Line strongly disputes that its HRA product was developed through reverse-engineering KYN and Dr. Leutzinger's statements, standing alone, do not support BioSignia's reverse-engineering theory.

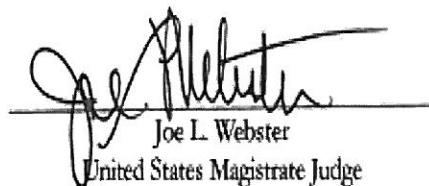
Plaintiff alleges that Life Line took confidential information and used it in creating its own HRA program, in violation of the agreements between the parties. Defendant strongly disputes these allegations. Both parties have submitted multiple affidavits supporting their arguments. At this stage of the proceeding, given the significant factual disputes present, Plaintiff has not submitted clear evidence which shows that Life Line breached the contract, breached its duty of good faith, or engaged in deceptive trade practices. Given the relatively strict standard governing the issuance of preliminary injunctions following *Winter* and *Real Truth*, based on the record before the court, BioSignia has simply not made a “clear

showing" of likelihood of success on the merits such as would allow this court to issue a preliminary injunction.

As the court noted in *Real Truth*, "[a] preliminary injunction is an extraordinary remedy." *Real Truth*, 575 F.3d at 345. Accordingly, under the new, stricter standard for preliminary injunctions, a court first considers the likelihood of success on the merits factor. Having done so, and having found that BioSignia has not met its burden of demonstrating the likelihood of success on the merits, the court "need not reach the merits of the parties' arguments concerning the remaining three [*Real Truth*] factors." *Dewhurst v. Century Aluminum Co.*, 731 F. Supp. 2d 506, 521 n. 23 (S.D.W. Va. 2010), *aff'd*, 649 F.3d 287 (4th Cir. 2011); *see also Warns*, 2012 WL 681792 at \*15. Accordingly, this court does not consider the likelihood of irreparable harm, the balancing of the equities or the public interest in the present matter.

### III. CONCLUSION

Based upon the foregoing, it is **RECOMMENDED** that Plaintiff's motion for a preliminary injunction (Docket Entry 33) be **DENIED**.



Joe L. Webster  
United States Magistrate Judge

Durham, North Carolina  
July 22, 2013